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Robert Johan Joseph Hageman

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EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,623	Applicant(s) HAGEMAN ET AL.	
	Examiner SATYANARAYANA R. GUDIBANDE	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 26-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I invention (claims 1, 18-25) and election of caseinates from milk as the preferred species of protein (claim 1); guanidine acetic acid as the preferred species of glycochamine (claim 1) ; folic acid as the preferred species of vitamin (claim 21); maltodextrin as the preferred species of food grade carbohydrate (claim 22); magnesium as the preferred species of mineral (claim 24); powder as the preferred form of composition (claim 25); and neurological disorders as the preferred form of disorder (claim 33) in the reply filed on 12/27/07 is acknowledged. The traversal arguments were answered in the office action dated 3/4/08.

Status of Pending Claims

Applicant's amendment to claims in the response filed on 2/12/10 has been acknowledged.

Claims 1 and 18-33 are pending.

Claims 2-17 have been canceled.

Claims 26-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/27/07.

Claims 1, 18-25 are examined on the merit.

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Any objections and/or rejections made in the office action dated 4/30/10 and not specifically discussed in its original or modified form here are considered withdrawn.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicants acknowledge that a copy of the cited reference "The AOAC Official Methods of Analysis, 1984, nr 43.263 and 43.264 is not currently available, but will submit a copy if it can be located".

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 18-25 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McCoy, 1956, American journal of Veterinary Research, 17, 90-97 in view of Hageman (WO 99/03365) further in view of Swaisgood, 1993, J. Dairy Sci., 76, 3054-3061 as set forth in the rejection dated 4/30/10. Response to applicant's arguments appears at the end of the reiterated rejection.

In the instant application, applicants claims a nutritional or pharmaceutical composition comprising: "a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis".

McCoy discloses a nutritional composition of low casein, supplemented with methionine and glycocyamine (page 91, column 1, bridging paragraph from page 90) for administering to dogs undergoing chemotherapy. The disclosure of McCoy that casein combined with glycocyamine was administered to dogs reads on the instant claim 1. The composition comprises of casein protein and glycocyamine. Glycine in free form is absent in the composition, however, it reads on the limitations of instant claim 18 as the amount of glycocyamine is 0.67% compared to 0.2% nitrogen from low casein component.

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Although, McCoy discloses a composition of casein and glycocyamine, it does not disclose that the casein protein used in the composition has a L-serine to glycine ratio more than 2.7:1 as required by the instant claims and other ingredients such as vitamins (folic acid), carbohydrate (maltodextrin), mineral (magnesium), etc. Items in the parenthesis are the elected species in the instant invention.

Swaigood, discloses that casein (milk protein, source: cow) is a mixture of proteins comprising α_1 -CN, α_2 -CN, κ -Cn and β -CN (table 1, page 3056). The molar ratio of L-serine:glycine (shown in the parenthesis in **bold**) differs in each of these proteins as follows: α_1 -CN (**8:9**), α_2 -CN (**6:2**), κ -Cn (**12:2**) and β -CN (**11:5**). The two casein proteins α_2 -CN (**6:2**), κ -Cn (**12:2**) have the L-serine:glycine ratio of more than 2.7:1. The milk proteins also comprises of 'phosphorylated serine' in the composition that would enhances the ratio of serine:glycine upon hydrolysis.

Hageman discloses a nutritional composition comprising casein as the protein (example 4, page 13) (reads on instant claims 1 and 18). Maltodextrin and sucrose as sugar (example 4, page 13) (reads on instant claim 22). Folic acid as the vitamin (example 4, page 13) (reads on instant claim 21). Magnesium as the mineral (example 4, page 13) (reads on instant claim 24). 0.5 to 40 g of Creatine (claim 4, page 16) (reads on instant claim 19 and 20). This reads on the recited ratio for energy metabolism precursor to creatine of 0.2:5. Pyridoxal as the aldehyde (claim 1, page 16) (reads on instant claim 23). Hageman also discloses that the mixture is homogenized, pumped into a heat exchanger where the water is evaporated and resulting product spray-dried and packed into cans (page 12, lines 24 and 25). This reads on the instant claim 25

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wherein the composition is in the powder form. It should be noted that the composition disclosed by Hageman is also free of free glycine.

It would have been obvious to one of ordinary skill in the art combine the teachings of McCoy, Swaisgood and Hageman to arrive at the instant nutritional composition comprising protein containing L-serine and glycine, glycoamine, carbohydrate, aldehyde, mineral, creatine and vitamins. McCoy discloses a nutritional composition comprising casein, glycoamine and Swaisgood discloses that casein protein fractions comprises of fragments that exhibits the ratio of serine:glycine more than 2.7. Hageman discloses a nutritional composition comprising casein, maltodextrin, folic acid, pyridoxal, creatine and magnesium. One of ordinary skill in the art would have been motivated to combine the teachings of McCoy, Swaisgood and Hageman because, McCoy discloses that to combat toxicity of cancer drugs during cancer treatment the body depletes "labile protein stores" as studied in the dogs by McCoy. McCoy discloses that a nutritional formulation comprising low casein supplemented with methionine and glycoamine reduced the excretion of urea nitrogen thereby increasing the retention of body nitrogen (page 93, column 1, bridging paragraph from page 92). Hence incorporation of glycoamine with casein is important in supplementing and retaining proteins in chemotherapy patients to overcome the toxic effects of the chemotherapy treatment which depletes proteins from the body. It should also be noted that applicants in their response (filed 2/12/10) to rebut the rejection under 35 USC 112 (written description) on pages 18-19 acknowledge that, "[A]dditionally, applicants note that the information available from Swaisgood provides examples of protein sources wherein the ratio of L-Serine:Glycine is more than 2.7:1. Applicants maintain that such information would provide sufficient guidance to one of skill in the art to allow them to select an

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appropriate source protein such that the ratio of L-Serine:Glycine is more than 2.7:1”. Therefore, one of ordinary skill in the art would incorporate glycoamine into nutritional compositions comprising casein proteins and beneficial ingredients of Hageman to arrive at the instant invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue the following:

1. Applicants argue that composition is either “i) free of **any** glycine, including the any glycine that may be present in the amino acid content of proteins and peptides present in the composition, or ii) if glycine is present, that the composition satisfies the requirement of a minimum L-serine:glycine weight ratio of 2.7:1. Applicants allege that office interpreted the claim that recites “free of glycine” as “composition of McCoy comprises casein protein and

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glycocyamine and is free of free glycine”. Applicants further state that the mixtures disclosed in McCoy and Hageman do contain casein and thus contain glycine.

2. Applicants argue that casein as that term understood by those of ordinary skill in the art refers to the protein precipitating from milk near pH 4.6 and refers to a mixture of several components which are difficult to separate and cite the reference of Walstra (Dairy Science Technology, 2nd Edition, 2006, pages 74, 75 and 79). Applicants further argue that Swaisgood itself states that the various caseins are difficult to resolve. Applicants further points out to reference of Handbook authored by Kessler and states that the table 23.12 shows that the ratio of L-serine to glycine is 2.6:1 and hence the instant invention is patentable over the prior art of the obviousness rejection.

Applicant's arguments filed 8/2/10 have been fully considered but they are not persuasive.

1. Applicants argument that the composition is “free of any glycine” is not adequately substantiated either in the Claim as recited or in the specification as disclosed. Applicants have elected ‘caseinates from milk protein” as the preferred species of protein in the composition and yet argue that that the casein and components of casein used in the cited prior art is different from the caseinates of the instant application. Applicants have not provided any sequences of caseinates that is completely devoid of glycine as claimed by them. More over, as illustrated in the rejection set forth above, applicants have acknowledged in their earlier remarks filed on 2/12/10 in response to 35 USC 112, Written Description rejection that “[t]he information

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available from Swaisgood provides examples of protein sources wherein the ratio of L-Serine:Glycine is more than 2.7:1. Applicants maintain that such information would provide sufficient guidance to one of skill in the art to allow them to select an appropriate source protein such that the ratio of L-Serine:Glycine is more than 2.7:1". This is a clear indication that one of ordinary skill in the art would look to Swaisgood for proteins and peptides that has a L-Serine:glycine ration more than 2.7:1. Therefore, applicant's argument that the composition is 'free of any glycine' is not adequately supported in the instant invention.

2. Applicants arguments that 'the casein as that term understood by those of ordinary skill in the art refers to the protein precipitating from milk near pH 4.6 and refers to a mixture of several components which are difficult to separate' is not persuasive either. Applicants seem to concentrate on only on the initial sentence on page 79 of the reference of Walstra (Dairy Science Technology, 2nd Edition, 2006, pages 74, 75 and 79). But the same reference does provide the methods by which the components of the product of acid hydrolysis of casein can be separated and characterized for example: by electrophoresis. Hence the separation of the components may be difficult but is not impossible. More over, as illustrated in the rejection above, the reference of Swaisgood clearly discloses that there are several components in the casein hydrolysate that conform to the L-Serine:glycine ratio more than 2.7:1. The reference of Handbook authored by Kessler provides the ratio for the casein in general and not the components of the acid hydrolysate of casein as disclosed in Swaisgood.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Commonly owned and different inventive entities

Claims 1, 19, 21-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,544,547 (‘547 patent) in view of McCoy, 1956, American Journal of Veterinary Research, 17, 90-97 and further in view of Swaisgood, 1993, J. Dairy Sci., 76, 3054-3061.

In the instant application, applicants claim a nutritional or pharmaceutical composition comprising: “a) a protein fraction containing peptides and proteins containing L-Serine and b) glycocyamine (GA), equivalents thereof, and mixtures thereof, wherein the composition is free of glycine, or glycine is present in the composition, the weight ratio L-Serine to Glycine is more than 2.7:1 as determined by hydrolysis”.

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‘547 Patent discloses a food composition comprising of proteinaceous material (reads on instant claim 1), carbohydrates (reads on instant claim 22), folic acid (reads on instant claim 21), magnesium (reads on instant claim 24), creatine (reads on instant claim 19) and pyridoxal (reads on instant claim 23). ‘547 Patent does not disclose that free glycine was present in the composition.

‘547 Patent does not disclose glycoamine in the food composition or discloses that the protein present in the composition has a ratio of greater than 2.7:1 for serine:glycine.

McCoy discloses a nutritional composition comprising casein and glycoamine and Swaisgood, discloses that casein (milk protein, source: cow) is a mixture of proteins comprising α_1 -CN, α_2 -CN, κ -Cn and β -CN (table 1, page 3056). The molar ratio of L-serine:glycine (shown in the parenthesis in **bold**) differs in each of these proteins as follows: α_1 -CN (**8:9**), α_2 -CN (**6:2**), κ -Cn (**12:2**) and β -CN (**11:5**). The two casein proteins α_2 -CN (**6:2**), κ -Cn (**12:2**) have the L-serine:glycine ratio of more than 2.7:1. The milk proteins also comprises of ‘phosphorylated serine’ in the composition that would enhances the ratio of serine:glycine upon hydrolysis.

It would have been obvious to one of ordinary skill in the art combine the teachings of Swaisgood and McCoy and ‘547 Patent to arrive at the instant nutritional composition comprising protein containing L-serine, glycoamine, carbohydrate, aldehyde, mineral, creatine and vitamins that is free of free glycine. McCoy discloses a nutritional composition comprising casein, glycoamine, Swaisgood, discloses that casein (milk protein, source: cow) is a mixture of proteins comprising α_1 -CN, α_2 -CN, κ -Cn and β -CN (table 1, page 3056) and ‘547 Patent discloses a nutritional composition comprising casein, maltodextrin, folic acid, pyridoxal,

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creatine and magnesium. One of ordinary skill in the art would have been motivated to combine the teachings of McCoy, Swaisgood and '547 Patent because, McCoy discloses that to combat toxicity of cancer drugs during cancer treatment the body depletes "labile protein stores" as studied in the dogs by McCoy. McCoy discloses that a nutritional formulation comprising low casein supplemented with methionine and glycocyamine reduced the excretion of urea nitrogen thereby increasing the retention of body nitrogen (page 93, column 1, bridging paragraph from page 92). Hence incorporation of glycocyamine with casein is important in supplementing and retaining proteins in chemotherapy patients to overcome the toxic effects of the chemotherapy treatment which depletes proteins from the body. It should also be noted that applicants in their response (filed 2/12/10) to rebut the rejection under 35 USC 112 (written description) on pages 18-19 acknowledge that, "[A]dditionally, applicants note Therefore, one of ordinary skill in the art would incorporate glycocyamine into nutritional compositions comprising proteins of Swaisgood and beneficial ingredients of '547 Patent to arrive at the instant invention. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue that "[a]s discussed above, neither the '547 patent, McCoy nor Swaisgood teach a composition that either free of glycine or contains L-Serine:glycine in a ratio of more than 2.7:1. Hence the references of '547 patent, McCoy or Swaisgood alone or in combination, does not teach the features of the instant invention.

Applicant's arguments have been considered and are not persuasive as discussed above in the rebuttal of the obviousness rejection and the as illustrated in the rejection itself. The double patenting rejection is proper and is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant's amendment to claim 1 and the arguments does not overcome the rejections on record. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654